IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IDENIX PHARMACEUTICALS LLC and UNIVERSITA DEGLI STUDI DI CAGLIARI, Plaintiffs, v. GILEAD SCIENCES, INC., Defendant.	**REDACTED PUBLIC VERSION** C.A. No. 14-846-LPS

PLAINTIFFS' OPENING BRIEF IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT ON DEFENDANT'S LATE-DISCLOSED DEFENSES BASED ON MERCK WORK

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I. NATURE AND STAGE OF THE PROCEEDINGS

This motion relates to Gilead's defenses that the asserted '054 and '597 patent claims are invalid based on alleged prior invention by Merck that Gilead raised for the first time in expert reports submitted long after discovery closed. Idenix moved to strike the late defenses, and on July 26, 2016, the Court denied that motion, although it determined that Gilead's late disclosures were prejudicial to Idenix. To "ameliorate the prior prejudice," it permitted Idenix to conduct additional discovery and, if premised on good faith, move for summary judgment. (D.I. 371.)

On August 5, 2016, Idenix requested reconsideration of the Court's ruling on Idenix's motion to strike, seeking a more balanced result whereby Gilead would take some responsibility for its "troubling" actions: it could still pursue certain of its late defenses but not the ones most prejudicial defense to Idenix, namely those that implicate a priority dispute and the need for Idenix to introduce a diligence case. (D.I. 374.) On August 22, 2016, Gilead opposed reconsideration. (D.I. 382.) Idenix's reconsideration motion remains pending.

Meanwhile, fact discovery on Gilead's belated defenses has closed and Dr. Secrist has been deposed. The record evidence is clear that Gilead's Merck-work defenses have no merit.

II. SUMMARY OF ARGUMENT

For each scenario fancied by Gilead alleging prior invention by Merck, Gilead cannot meet, as a matter of law, at least one necessary element to establish an invalidity defense. Raising these defenses late and even seeking summary judgment on them to no avail, Gilead sent this case on a wild detour. The only reason Gilead injected these defenses into the case is to cast a prejudicial shadow over the inventions of the Idenix scientists. There is no merit to the defenses, and they should be rejected as a matter of law.

First, Gilead cannot use Merck's 1998 BVDV test as prior invention because (a) Merck's 1998 BVDV test indisputably was not a method of treatment for hepatitis C virus as required by

the asserted claims; (b) the undisputed evidence shows that Merck never appreciated that those test results demonstrated anything inventive, much less that they demonstrated the methods of the claimed inventions; and (c) the undisputed evidence shows that Merck permanently shelved that 1998 effort—establishing abandonment, suppression, or concealment as a matter of law, even if one wrongly assumed the 1998 BVDV test constituted an "invention." Gilead itself moved for summary judgment on this defense, admitting no fact dispute for at least this defense.

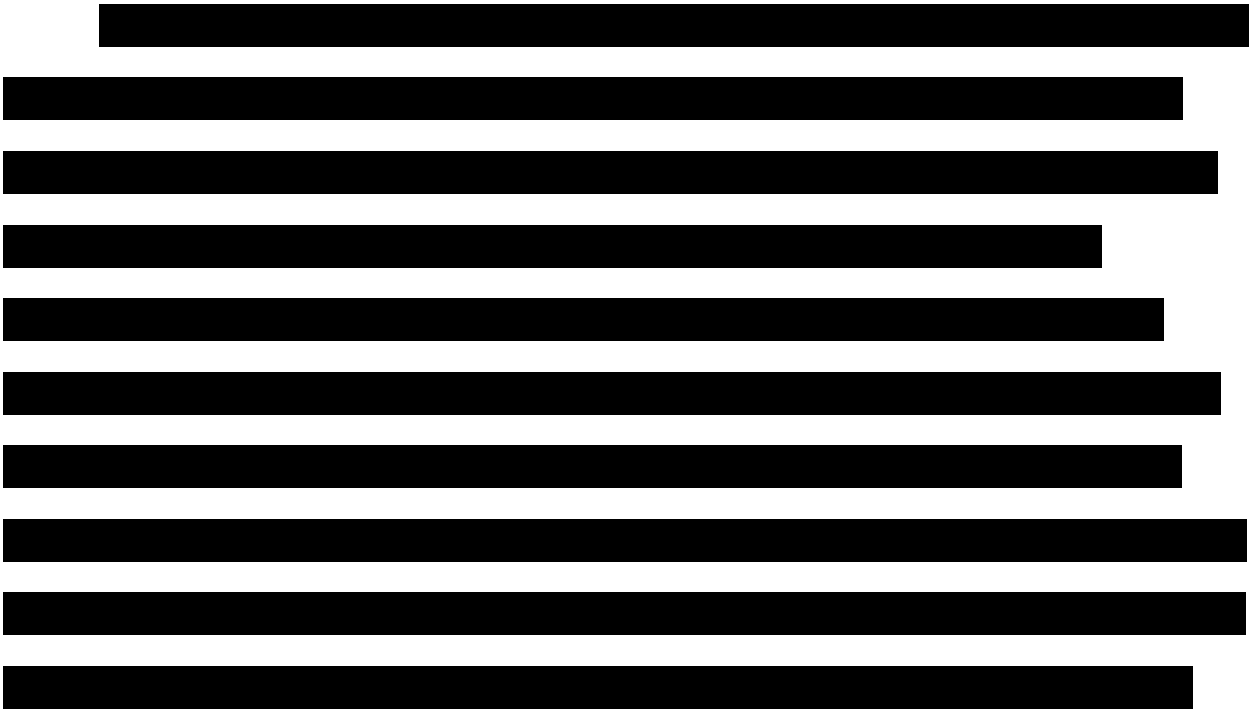
Second, there is no fact dispute about Merck's later work in the fall of 2000 leading up to its January 2001 patent application, either—it, too, does not antedate Idenix's inventions to qualify as prior art. As an initial matter, Idenix intends to show at trial that it is entitled to its May 23, 2000 priority date, rendering this asserted art too late on its face. Gilead challenges Idenix's claim to the May 23, 2000 priority date. But, even if one assumes Gilead's assertion of a later, May 23, 2001 priority date, the 2000-2001 Merck work would still fail to antedate Idenix's inventions. The undisputed evidence shows that Idenix conceived before Merck reduced any invention to practice, and that Idenix diligently reduced its inventions to practice.

III. STATEMENT OF FACTS

A. Conception And Reduction To Practice Of Idenix's Patented Inventions

Drs. Jean-Pierre Sommadossi and Paolo La Colla are the two inventors of the '054 and '597 patents. [redacted]

On May 23, 2000, the inventors filed a provisional patent application directed to their invention. There is no dispute that Drs. Sommadossi and La Colla first conceived of the claimed inventions in the first half of 2000, and certainly by the time they filed their provisional application in May of that year. (Ex. 7, Secrist Tr. at 480:17-481:9; Ex. 8, at ¶ 32; Ex. 2, at ¶ 49.) A year later, on May 23, 2001, Drs. Sommadossi and La Colla filed a non-provisional application that ultimately issued as the '054 patent. (Ex. 22, IDXDE00001127.) The '597 patent, which is a continuation of the '054 patent, claims the same May 23, 2000 priority date as the '054 patent. (Ex. 9, IDXDE00001215.) For purposes of this motion, the filing of the non-provisional application constitutes the inventors' latest constructive reduction to practice.



Dr. Gosselin's declaration describes the daily, continuous work of the chemists under his direction and supervision who synthesized 2'-methyl and 2'-branched ribonucleosides between August 1, 2000, and May 23, 2001. (Ex. 6, at ¶ 3.) Likewise, Dr. Standring's declaration describes all the biological testing that the scientists working under his direction performed on

2'-methyl and 2'-branched ribonucleosides between those same dates. (Ex. 10, at ¶ 3.)

B. Merck's Work From 1998 To 2001

1. Merck's 1998 Testing And Abandonment

[redacted]

2. Merck's Conception In September 2000 Of HCV Treatment Using 2'-Methyl Adenosine

[redacted]

[redacted]

Merck's September 2000 testing and subsequent work led it to file U.S. Provisional Application 60/263,313 on January 22, 2001, which led to Merck's U.S. Patent No. 7,202,224 that claims priority to the '313 application. (Ex. 17, at ¶¶ 18-20; Ex. 2, at ¶¶ 61, 63, 67.)

IV. ARGUMENT

Summary judgment shall be granted where "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A non-movant's assertion that a fact is genuinely disputed must be supported by evidence "such that a

reasonable jury could return a verdict for the nonmoving party"; the "mere existence of *some* alleged factual dispute between the parties" will not suffice. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986) (emphasis in original).

Gilead, through its experts, argues that Idenix's inventions are invalid because various individuals at Merck invented the subject matter of the asserted claims of the '054 and '597 patents before Idenix did or because the asserted claims would have been obvious in light of the Merck work. [redacted] For each of these defenses, Gilead must show, as a threshold matter, that the asserted Merck work qualifies as prior art.

Gilead invokes 35 U.S.C. §§ 102(e)(2) or 102(g) to claim the Merck work as prior art. Section 102(e)(2) covers U.S. patents where the application was filed before the priority date of the asserted patent. *See* 35 U.S.C. § 102(e)(2) (pre-AIA). Section 102(g) covers prior inventions "made in this country by another inventor who had not abandoned, suppressed, or concealed it." 35 U.S.C. § 102(g) (pre-AIA); *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1577 (Fed. Cir. 1996) (Section 102(g) "contains the basic rule for determining priority"). Under either provision, priority is established if the inventor reduced an invention to practice first or was first to conceive and then was diligent in reducing to practice. *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 252 F.3d 1306, 1314 (Fed. Cir. 2001) (vacated on other grounds). "Priority is a question of law, based on subsidiary findings of fact related to conception, reduction to practice, and diligence." *Alexsam, Inc. v. Gap, Inc.*, 621 F. App'x 983, 988 (Fed. Cir. 2015). As an ultimate

legal issue, priority is highly amenable to summary judgment.

The defendant bears the burden, at all times, to prove an invalidity defense, including prior invention, by clear and convincing evidence. *See Apotex USA, Inc. v. Merck & Co.*, 254 F.3d 1031, 1037-38 (Fed. Cir. 2001) ("[T]he ultimate burden of persuasion remains with the party challenging the validity of the patent."). Although the burden of production shifts, the defendant's burden of persuasion never does. Thus, if the defendant presents sufficient evidence of invalidating prior art or prior invention, the patentee has the burden of "com[ing] forward with evidence" that the prior art is not actually prior art, the prior invention was abandoned, suppressed, or concealed, or the prior art does not actually invalidate the claims. *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1573 (Fed. Cir. 1985) (If the defendant "establish[es] a legally sufficient *prima facie* case of invalidity," the patentee "is then obligated to come forward with evidence to the contrary."). If the patentee produces such evidence, then the defendant bears the ultimate burden to "convince the court" of invalidity by clear and convincing evidence, *e.g.*, that the patentee is not entitled to the benefit of an earlier invention date, that the prior invention was not abandoned, suppressed, or concealed, or that the art is prior art that invalidates the claims. *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1328 (Fed. Cir. 2008).

A. The Undisputed Evidence Shows That Merck's 1998 Test Is Not Prior Art

Gilead's invalidity arguments based on Dr. Wolanski's 1998 BVDV test should be rejected as a matter of law because the undisputed evidence shows that the test cannot be invalidating prior art, for three independent reasons. *First*, the 1998 BVDV test does not constitute an actual reduction to practice of an invention claiming "a method for the treatment of a hepatitis C virus infection," as required to meet all of the limitations of the asserted claims. Gilead has not proffered and cannot proffer any evidence that anyone at Merck used 2'-methyl adenosine to treat an HCV infection when it ran the 1998 BVDV test. *Second*, nobody at Merck

appreciated that it had invented anything, let alone a treatment for HCV. As such, the 1998 test cannot amount to either conception or reduction to practice to constitute "invention." *Third*, even assuming it could, any "invention" was abandoned.

1. Dr. Wolanski's 1998 BVDV Test Was Not A Prior Invention Of A Method For The Treatment Of HCV

To use Dr. Wolanski's 1998 test as anticipatory prior art under Section 102(g), Gilead must, in addition to establishing the quintessential markers of invention of conception and reduction to practice, show that the test "performed a process that met all the limitations" of the asserted claims. *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1332, 1337 (Fed. Cir. 2001). Thus, Gilead must show that the 1998 BVDV test performed "[a] method for the treatment of a hepatitis C virus infection." (*E.g.*, Ex. 9, at Claim 1.)

Gilead cannot make that showing. Indeed, Gilead cannot identify any evidence in the record demonstrating that the 1998 BVDV assay of 2'-methyl adenosine constituted a method of treating an HCV infection.

[redacted]

[redacted] So there is not a shred of evidence from either Gilead or Idenix that the 1998 BVDV test was an actual reduction to practice of a method of treating HCV. As a matter of law, Gilead's unsupported argument must fail.

Nor can the 1998 test be used as a prior art reference for obviousness. As the following sections show, that test was not an invention of ***anything***, much less a method of treating HCV.

2. Nobody At Merck Appreciated That The 1998 Test Was An Invention

Dr. Wolanski's 1998 BVDV test does not constitute prior art because it fails the "contemporaneous recognition and appreciation of the invention" requirement for Section 102(g) art. For an invention to exist, the alleged prior inventor must have appreciated what he invented. "It is well-settled that conception and reduction to practice cannot be established nunc pro tunc. There must be *contemporaneous recognition and appreciation* of the invention . . . ." *Estee Lauder Inc. v. L'Oreal, S.A.*, 129 F.3d 588, 593 (Fed. Cir. 1997) (emphasis in original); *see also Genentech, Inc. v. Chiron Corp.*, 220 F.3d 1345, 1352 (Fed. Cir. 2000) (Reduction-to-practice prong requires "recognition and appreciation that the tests were successful."); *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1063 (Fed. Cir. 2005) ("Conception requires that the inventor appreciate that which he has invented."). Moreover, the "appreciation" analysis "requires objective corroboration of the inventor's subjective beliefs." *Id.* at 1064, 1066 (Where there is no "corroborating evidence of" an inventor's purported belief in achieving an invention, there is no invention."); *Cooper v. Goldfarb*, 154 F.3d 1321, 1330 (Fed. Cir. 1998) ("In order to establish an actual reduction to practice, an inventor's testimony must be corroborated by independent evidence."). Also, the appreciation must be contemporaneous with the purported invention. *Mycogen*, 252 F.3d at 1314 ("Conception requires contemporaneous recognition and

appreciation of the limitations of the claimed invention, not merely fortuitous inherency."); *Cooper v. Goldfarb*, 240 F.3d 1378, 1386 (Fed. Cir. 2001) (Reduction to practice requires showing that inventor "contemporaneously appreciate[d] that the embodiment…met all the limitations of the" claims.).

Thus, "it is not enough that a party adduce evidence that objective test results comport with an inventor's testimony concerning his state of mind." *Invitrogen*, 429 F.3d at 1065. Rather, the evidence must show that the alleged prior inventor timely interpreted or evaluated the results, and understood them to show the existence [of an] invention." *Id.* "[A]n accidental, unappreciated reduction to practice should not constitute a 'true' reduction to practice for the purposes of determining priority of invention or anticipation pursuant to section 102(g)." *Mycogen*, 243 F.3d at 1336.

Here, the undisputed evidence establishes that, between 1998 and Idenix's conception in 2000 (and beyond), nobody at Merck appreciated the 1998 BVDV test of 2'-methyl adenosine as an invention of anything, much less an invention with the features of Idenix's patent claims. There is no evidence that Dr. Wolanski or anyone else at Merck recognized contemporaneously anything special about the 1998 testing, and certainly none discerned from the testing that 2'-methyl adenosine could be a candidate compound for the treatment of HCV. As in *Estee Lauder*, where the Federal Circuit reversed a determination of invalidity, there is "simply no basis upon which to conclude" that in 1998, Merck determined it had an invention. 129 F.3d at 595.

[redacted]

[redacted]

Gilead can point to no contrary evidence to create a fact dispute. [redacted] Thus, despite having the heavy burden, Drs. Secrist and Seeger (Gilead's only witnesses who says the 1998 BVDV test was a reduction to practice) have no idea what Dr. Wolanski and others appreciated. [redacted]

Moreover, Gilead has no corroborating evidence of a subjective belief of invention.

Gilead has no evidence that anyone else at Merck, much less the inventors named on Merck's patents and applications, "timely interpreted or evaluated" the results of the BVDV test and "understood them to show the existence [of an] invention" for the treatment of HCV. *Invitrogen*, 429 F.3d at 1065. At most, the evidence shows that, years after the 1998 testing, other scientists reviewed the results. [redacted] Not being contemporaneous, that evidence is legally irrelevant. *See Cooper*, 240 F.3d at 1386 ("Subsequent testing or later recognition may not be used to show that a party had contemporaneous appreciation of the invention.").

Besides, Gilead's cited evidence is no more enlightening than Dr. Wolanski's sparse notations. [redacted] In fact, the evidence fails to show any contemporaneous appreciation of the 1998 test as invention of anything, and thus cannot constitute either anticipatory prior invention or prior art for purposes of obviousness since the same requirements apply. *See E. I.* d*u Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1437 (Fed. Cir. 1988) (Prior work may "be used as prior art in a § 103 context so long as it satisfied the requirements of § 102(g)."). For instance, there is no evidence that anyone at Merck had any appreciation of that test even to treat BVDV, the assay

in which the test was run. At most, Dr. Wolanski recognized that the compound was active against BVDV, but that is not the same as recognizing it could be used to treat BVDV.

[redacted] To qualify as Section 102(g) art, whether for Section 102 or Section 103, it must be the inventor who recognized and appreciated the "invention," not a hypothetical artisan. *See Manning v. Paradis*, 296 F.3d 1098, 1104-05 (Fed. Cir. 2002); *Mycogen*, 252 F.3d at 1314. With the undisputed facts showing that neither Dr. Wolanski nor anyone else at Merck appreciated the 1998 testing as inventive at all, that work cannot serve as prior art as a matter of law for either Sections 102 or 103.[1]

3. Merck Abandoned, Concealed, Or Suppressed The 1998 Test Results

Even assuming wrongly that someone at Merck conceived and reduced to practice an invention in 1998, the undisputed facts show that it was abandoned, suppressed, or concealed.

Section 102(g) disqualifies prior inventions "that have been 'abandoned, suppressed, or concealed,'" *e.g.*, where a prior inventor "unreasonabl[y] delay[ed] in making the invention publicly known." *Fleming v. Escort Inc.*, 774 F.3d 1371, 1378 (Fed. Cir. 2014). The purpose of the abandonment-suppression-concealment disqualification is to "encourage[] prompt public

[1] [redacted]

disclosure of an invention by penalizing the unexcused delay or failure of a first inventor to share the 'benefit of the knowledge of the invention' with the public." *Checkpoint Sys., Inc. v. U.S.I.T.C.*, 54 F.3d 756, 761 (Fed. Cir. 1995). Thus, the "failure to file a patent application, to describe the invention in a published document, or to use the invention publicly, within a reasonable time after first making the invention may constitute abandonment, suppression, or concealment." *Fox Grp., Inc. v. Cree, Inc.*, 700 F.3d 1300, 1306 (Fed. Cir. 2012); *see also Lutzker v. Plet*, 843 F.2d 1364, 1367 (Fed. Cir. 1988) (Abandonment, suppression, or concealment can be inferred from "an unreasonable delay between the actual reduction to practice and the filing of a patent application."); *Shindelar v. Holdeman*, 628 F.2d 1337, 1342 (C.C.P.A. 1980) (finding suppression or concealment because there was no reasonable explanation for two-plus-year delay between reduction to practice and filing patent application). Like the priority dispute more broadly, whether another party abandoned, suppressed, or concealed an invention is "a matter of law" and therefore highly amenable to summary judgment. *CheckPoint*, 54 F.3d at 761.

Here, there is absolutely no evidence that Merck worked to share the so-called invention with the public. [redacted]

[redacted] Merck's undisputed abandonment of 2'-methyl adenosine disqualifies its 1998 testing as prior art for both Section 102 and Section 103 purposes.

Of course, in the fall of 2000, Merck did discover that 2'-methyl adenosine could be useful as a treatment for HCV. But this work was completely independent of any knowledge of the 1998 BVDV test results, and the undisputed evidence confirms that. [redacted] If any further confirmation were needed, Merck's January 2001 provisional patent application disclosing 2'-methyl adenosine mentions nothing about evaluation of that compound in a BVDV assay. In short, with no relationship between the 1998 BVDV testing and Merck's 2000 discovery of the HCV activity of 2'-methyl adenosine, Gilead cannot establish that

Merck did not suppress, conceal, or abandon its 1998 testing.

Finally, Gilead's experts cite Merck's general engagement in HCV research after the 1998 BVDV test, as purported evidence that Merck did not abandon any "invention" based on that test. [redacted] Those arguments are legally irrelevant. *First*, Merck's work (by other scientists) from 1998 through mid-2000 on other compounds and other viruses do not have any relation to Dr. Wolanski's 1998 BVDV test or to 2'-methyl adenosine. *Second*, there is not a scintilla of evidence that any of this work was done at the direction of Dr. Wolanski as required to show the **inventor** did not abandon. Thus, none of this work creates any fact disputes to preclude summary judgment.

As the Federal Circuit recently held in *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952 (Fed. Cir. 2014), work must relate to the purported invention to be relevant.[2] In *Allergan*, work on the relationship between eyedrops and hair growth did not corroborate an invention claiming the *topical* application of a product: "The problem is that to the extent there is any documentary evidence, it does not relate to the claimed invention of the [patent at issue]." *Id.* at 967-68. So too, here, where Merck's general research on other compounds for treatment of HCV does not relate Dr. Wolanski's alleged prior invention—a method of using 2'-methyl adenosine for the treatment of HCV. Nor does Merck's testing of 2'-methyl adenosine for various other diseases

[2] The work must also be done at the direction of the inventor. *Cooper v. Goldfarb*, 154 F.3d at 1331 (For other work to inure to the inventor, he must show "that the other person was working either explicitly or implicitly at the inventor's request.").

relate to the claimed invention—*i.e.*, the use of certain compounds to treat HCV.

B. The Undisputed Evidence Shows That Merck's August/September 2000 Testing And '224 Patent Are Not Prior Art Because Idenix Conceived Before Merck And Was Reasonably Diligent In Reducing Its Invention To Practice

Gilead's defenses based on Merck's September (and August) 2000 testing of 2'-methyl adenosine and Merck's '224 patent, which claims priority to Merck's January 2001 provisional application that relates to Merck's work in September 2000 and beyond, also fail as a matter of law. As an initial matter, none of this asserted art applies if Idenix is entitled to its May 23, 2000 priority date—that date would make Merck's work beginning in August 2000 and its '224 patent, with a January 2001 priority date, too late to qualify as prior art. [redacted] But even with a priority date of May 23, 2001, the asserted art is too late. There is no dispute that Drs. Sommadossi and La Colla conceived of their invention by May 2000, before Merck did in September (or August) 2000. Moreover, the declarations of Drs. Gosselin and Standring demonstrate that Idenix diligently worked on the invention leading up to the priority date of May 23, 2001, when the inventors filed their non-provisional application. Thus, the 2000 testing and Merck's '224 patent with a priority date of January 2001 are not prior art under Sections 102 or 103 for either possible priority date of Idenix.

In determining priority, "there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other." 35 U.S.C. § 102(g) (pre-AIA). Diligence is measured "from a date just prior to the other party's conception to . . . the date of reduction to practice by the party first to conceive," which is known as the "critical period." *Monsanto Co. v. Mycogen Plant Sci., Inc.*, 261 F.3d 1356, 1363

(Fed. Cir. 2001). To establish diligence, "the basic inquiry is whether . . . there was reasonably continuing activity to reduce the invention to practice." *Tyco Healthcare Grp. LP v. Ethicon Endo-Surgery, Inc.*, 774 F.3d 968, 975 (Fed. Cir. 2014) (citation omitted) (affirming determination of reasonable diligence "as the record contains lab results, reports showing due dates and milestones, and similar types of evidence demonstrating diligent reduction to practice within the relevant time period"). "Proof of reasonable diligence, however, does not require a party to work constantly on the invention or to drop all other work." *Monsanto*, 261 F.3d at 1369 (citation omitted). Moreover, the work need not be performed by the inventor as long as he "authorize[d] another to reduce his invention to practice." *Solvay S.A. v. Honeywell Int'l Inc.*, 742 F.3d 998, 1006 (Fed. Cir. 2014). Although diligence is considered in light of all the circumstances, where the record is so one-sided that no reasonable jury could find lack of diligence, summary judgment is appropriate. *See Fairchild Semiconductor Corp. v. Power Integrations, Inc.*, 100 F. Supp. 3d 357, 370 (D. Del. 2015) (granting summary judgment where the inventors "were continuously diligent in reducing the invention to practice during the entire critical period"); *Stamicarbon BV v. Sepracor, Inc.*, No. CIV.A. 97-8-GMS, 2001 WL 253118, at *6 (D. Del. Mar. 12, 2001) (granting summary judgment of reasonable diligence).

Here, Idenix's more than diligent efforts on its patented inventions pass the test with flying colors to antedate Merck 2000-2001 work as a matter of law. The one-sided evidence overwhelmingly shows that Idenix scientists, under the direction of the inventors, continuously worked on the synthesis and testing of 2'-methyl ribonucleosides during the critical period—*i.e.*, from just before Merck's August/September 2000 (or January 2001) conception date until Idenix's May 23, 2001 non-provisional filing date. The declarations of Dr. Gosselin and Dr. Standring show in great detail that, on nearly every day during the critical period, Idenix

scientists worked on the invention. No reasonable jury could find lack of diligence.

Gilead's experts lob nitpicks that are insufficient to create any genuine fact dispute. [redacted] Such expert testimony lacking "a factual foundation cannot defeat a motion for summary judgment." *Advo, Inc. v. Phila. Newspapers, Inc.*, 51 F.3d 1191, 1198 (3d Cir. 1995); *Kosierowski v. Allstate Ins. Co.*, 51 F. Supp. 2d 583, 595 (E.D. Pa. 1999) ("The mere presence of an expert opinion supporting the non-moving party's position does not necessarily defeat a summary judgment motion; rather, there must be sufficient facts in the record to validate that opinion."), *aff'd*, 234 F.3d 1265 (3d Cir. 2000).

Second, [redacted] But even setting aside this disputed work for the sake of argument and accepting them as irrelevant, the remaining evidence of reasonable diligence is still overwhelming and sufficient for summary judgment. As Exhibit 21 shows, Dr. Secrist's quibbles challenge a relatively small amount of the total work conducted during the critical period.[3]

Moreover, constant effort is not required. In *Stamicarbon*, the court found that "the

[3] Exhibit 21 color-codes entries for the work done by certain Idenix employees Dr. Secrist disputes in their entirety. As the calendar makes clear, the vast majority of those disputed entries constitute work performed on days other Idenix scientists were conducting work that cannot be disputed (the remaining, black entries) and which themselves establish ongoing diligence as a matter of law.

burdens of being a 'small startup' company made it difficult for the company to work on the project everyday," and stated this was "a valid excuse for inactivity." 2001 WL 253118, at *6. "The law requires only reasonable (and not heroic) diligence." *Id*. (citation omitted). If the inventors "were doing the things reasonably necessary to reduce the idea to practice, then they were diligent *even if they did not actually work on the invention each day*." *Id*., at *7 (citation omitted) (emphasis in original); *see also Hybritech Inc v. Abbott Labs.*, No. CV 86-7461/AK (PX), 1987 WL 123997, at *7 (C.D. Cal. July 14, 1987) ("[I]t is not necessary that an inventor be working on the invention every day."), *aff'd*, 849 F.2d 1446 (Fed. Cir. 1988); *Johns Hopkins Univ. v. 454 Life Scis. Corp.*, No. 13-1853-LPS, 2016 WL 1948818, at *5 (D. Del. May 2, 2016) ("[E]vidence of activity on every single day" is not required if there is "a satisfactory explanation."). Thus, in *Stamicarbon*, evidence showing that the inventor worked on the invention 64% of the time during the critical period (14 out of 22 business days) established as a matter of law that he was diligent. 2001 WL 253118, at *6. Any "short gaps"— three single days, two days in a row, and another three days in a row—could not demonstrate otherwise. *Id.* In this case, the scientists at Idenix—itself a start-up company with competing resources—worked on the invention nearly every business day for the entire critical period. (Ex. 6; Ex. 10; Ex. 21; Ex 23.)

Finally, Dr. Seeger's opinions regarding Merck's diligence are of no moment. (*E.g.*, Ex. 8, at ¶¶ 16, 28.) Because Idenix conceived of the inventions before Merck, Idenix's reasonable diligence in reducing its inventions to practice disqualifies Merck's work as prior art, regardless whether Merck was equally diligent. The party that conceives before and is reasonably diligent in later reducing to practice is the first inventor. *See* 35 U.S.C. § 102(g) (pre-AIA).

V. CONCLUSION

Summary judgment is proper that Merck's work cannot invalidate the '054/'597 patents.

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